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Title

Evaluation of Transvaginal Peritoneal Surgery in Young Female Patients

Running head

Transvaginal approach in young women

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Abstract

Background. The transvaginal approach is being used for natural orifice transluminal endoscopic surgery (NOTES), and reports of the clinical use of transvaginal NOTES have increased rapidly. However, hasty use of a transvaginal route may cause unexpected complications. Infertility or dyspareunia after transvaginal NOTES in young women is one of the most important issues to be resolved. The purpose of this study was to assess long-term complications, including infertility and dyspareunia, after transvaginal peritoneal surgery.

Methods. An anonymous questionnaire was sent to 73 young patients who had undergone ovarian cystectomy using a transvaginal approach from 2003 to 2011. The questionnaire contained 15 questions; 6 dealt with fertility, and 8 dealt with discomfort after surgery. A 5-point scale was used to evaluate patients' overall satisfaction with surgery.

Results. Forty-four (60%) questionnaires were returned. The patients' mean age was 33.0 years, and the mean postoperative follow-up period was 16.5 months. Of responders under 40 years of age, 24 did not use contraception, and 9 (38%) conceived. The pregnancy rate among women under 30 years of age was 60%. Two (5%) women

reported temporary dyspareunia 1 month after surgery, but none developed permanent dyspareunia. The average patient satisfaction score was 4.12.

Conclusions. There was no evidence to suggest that transvaginal peritoneal surgery causes infertility or dyspareunia. The majority of patients gave a high evaluation to vaginal ovarian cystectomy, suggesting the usability of a transvaginal approach for intraperitoneal surgery in young premenopausal women.

Key words: transvaginal surgery; NOTES; ovarian cystectomy; culdotomy; infertility; dyspareunia

Introduction

Natural orifice transluminal endoscopic surgery (NOTES) has become a focus of great interest (1-4). In NOTES, natural orifices such as the mouth, anus, urethra, and vagina are used as ports of entry into the peritoneal cavity through which flexible or rigid endoscopic devices are passed to perform the surgery. Currently, transvaginal access appears to be the most practical for NOTES, and reports of the clinical use of transvaginal NOTES have increased rapidly, although such surgery is obviously limited to female patients (5,6).

Hasty use of a transvaginal route, however, may cause unexpected complications. According to a questionnaire administered to gynecologists, postoperative infections, visceral lesions, adhesions, infertility, and dyspareunia were mentioned as complications following transvaginal NOTES (7). An anonymous questionnaire given to female medical staff, patients, and the general population with regard to transvaginal NOTES revealed that their worries were related to fears regarding fertility and postoperative sexuality (8). Preclinical studies using animal models are insufficient to identify all complications that may occur in humans, especially for infertility and dyspareunia, for

which no animal models are appropriate. Before transvaginal NOTES becomes widely used, surgeons need to be aware of the incidence of such complications.

Since 2003, we have performed transvaginal ovarian cystectomy for 73 young women in whom ovarian cysts were removed through a 3-cm defect in the vaginal wall (9-13). We recently reported that vaginal ovarian cystectomy to treat a dermoid cyst was equivalent to laparoscopic cystectomy with respect to invasiveness (13). All transvaginal cystectomies were completed without intra-operative complications, and there were no differences in operating time, blood loss, and postoperative infection between the two procedures. In most cases, a completely vaginal approach without visible scars was realized. In this study, in order to estimate the long-term complications, each patient was asked to complete a questionnaire including questions about fertility and discomfort after surgery. This is the first, well-organized report to address the complications after transvaginal ovarian cystectomy.

Ovarian cystectomy performed is not transvaginal NOTES, because no endoscope is used. A transvaginal approach, however, is common to both. In transvaginal NOTES, there have been no reports that have examined the real effect of a transvaginal approach. Because of the cosmetic merit, having no scars on the abdominal wall is valuable,

especially in young women; thus, investigating the complications in young patients is very important and clinically significant. The results of our survey may be useful in evaluating unexpected complications after not only transvaginal ovarian cystectomy, but also transvaginal NOTES.

Materials and Methods

A 5-page questionnaire was sent by mail to 73 patients who underwent ovarian cystectomy via a transvaginal approach. On the first page of the questionnaire, the age of the patient (in 5-year intervals), the postoperative follow-up period (in 6-month intervals), and the histology of each cyst were already entered. The questionnaire included 15 questions, 6 of which dealt with obstetrical history before or after surgery, and 8 of which dealt with gynecological discomfort before or after surgery. The last question asked the patient to evaluate her transvaginal ovarian surgery using a 5-point scale. This survey was administered in February 2007, March 2008, January 2010, and December 2011 to patients who had undergone surgery more than 6 months earlier. Each patient was asked to return the answers anonymously to our department using a self-addressed, stamped envelope provided with the questionnaire.

A total of 73 patients underwent transvaginal ovarian cystectomy between April 2003 and May 2011 at Kanazawa University Hospital or Sagawa Clinic.

Laparoscopically supported vaginal ovarian cystectomy is a newly proposed operative approach, in which the ovarian cystectomy is initially approached transvaginally; in rare cases in which a vaginal approach is impossible due to failed

culdotomy, intrapelvic adhesions, or uncontrolled bleeding, laparoscopy is used to complete the operation (10,13). Without conversion to laparoscopy, ovarian cystectomy is performed directly through the culdotomy. With conversion to laparoscopy, cystectomy is performed using a traditional laparoscopic procedure with conventional laparoscopic devices. Of the 73 patients in the present study, 70 underwent only a transvaginal procedure, and the remaining 3 underwent both transvaginal and laparoscopic procedures. All cystectomies were accomplished successfully without a laparotomy.

For the entry into the intraperitoneal cavity, the new culdotomy techniques named Culdotomy 2U and Culdotomy 4S2U were used (11,12). In both methods, transvaginal ultrasound identified the safe incision point on the vaginal wall, and a newly developed device, the umbrella Hakko needle, was used as a guide for the entry into the cul-de-sac. A vaginal ultrasound probe with a needle guide was inserted into the vagina, and the ovarian cyst (2U) or an artificially created saline solution space in the cul-de-sac (4S2U) was punctured with an umbrella Hakko needle via the center of the posterior vaginal fornix. The route to the intraperitoneal cavity was created by cutting the vaginal wall along the Hakko needle with an electric scalpel. The incision

on the vaginal wall was about 3 cm long. After removal of the surgical specimen via the vaginal defect, the opening was transvaginally closed with sutures.

Normally distributed data were reported as the mean \pm standard deviation, whereas skewed data were reported as the median with range. Some data were reported as percentage. To test differences, Student's *t* test was used for normally distributed data, whereas Mann–Whitney *U* test was used for skewed data. Values of $P < .05$ were considered statistically significant.

The 73 patients' mean age was 31.9 years with an SD of 7.0 years, and the mean postoperative follow-up period was 16.7 months with an SD of 8.9 months. Histological examination of the resected specimens showed 40 (55%) teratomas, 14 (19%) serous cystadenomas, 13 (18%) endometriomas, 4 (5%) mucinous cystadenomas, and 2 (3%) paratubal cysts. Forty-eight (66%) patients were multigravidas and 35 (48%) were pluriparas.

Results

A total of 44 (60%) patients returned completed questionnaires. The mean age of the 44 responders was 33.0 years with an SD of 6.1 years, and the mean postoperative follow-up period was 16.5 months with a SD of 8.6 months. The histological type of ovarian cyst was 25 (57%) teratomas, 6 (14%) endometriomas, and 13 (29%) others. Twenty-eight (64%) patients were multigravidas, and 20 (45%) were pluriparas. There were no significant differences between patients and responders in the characteristics evaluated.

Of the 40 responders under 40 years of age, 24 did not use contraception. Their mean age was 31.5 years with an SD of 5.3 years, the mean postoperative period was 15.8 months with a SD of 6.5 months, and the multigravida rate was 54%. Of these 24 women, 9 (38%) conceived, and there were 12 pregnancies among the 9 women (Figure 1a). The mean age of these 9 women was 29.2 years with an SD of 5.6 years, the mean postoperative period was 18.3 months with a SD of 9.1 months, and the multigravida rate was 56%, while the mean age of the residual 15 women was 32.8 years with an SD of 4.8 years, their mean postoperative period was 14.2 months with a SD of 3.8 months, and their multigravida rate was 53%. The pregnancy rate of women

under 30 years of age was 60%, while that of women over 30 years of age was 21% (Figure 1b). The pregnancy rate among pregnant women with a postoperative follow-up period under 18 months was 28%, and that of those with a postoperative period over 18 months was 67% ($p = 0.09$). The courses of the 12 pregnancies were as follows: 2 (16%) spontaneous abortions, 5 (42%) ongoing pregnancies, and 5 (42%) deliveries. The 5 deliveries were all uneventful, transvaginal deliveries at term. There were no cases of Cesarean section before or after transvaginal cystectomy.

Gynecological discomfort was considered in 2 categories: that which existed before surgery and that which occurred only after surgery.

Discomfort that occurred only after surgery included dyspareunia, abnormal genital bleeding, and dysmenorrhea. The median time to first intercourse after surgery was 2 months, ranging from 1 to 12 months (Figure 2). Two (5%) women complained of dyspareunia 1 month after surgery, but this symptom disappeared 2 months after surgery. Two (5%) women complained of abnormal genital bleeding: 1 episode of genital bleeding occurred during sexual intercourse 1 month after surgery, but it then resolved spontaneously 2 months after surgery; the other bleeding episode occurred regularly in the middle of the menstrual cycle. Three (7%) women with endometriomas

complained of dysmenorrhea. In 1 pregnant woman, the dysmenorrhea disappeared after delivery. In the residual cases, dysmenorrhea continued for 1 year before disappearing in one patient, and in the other patient, it continued.

Discomfort that existed before surgery included dyspareunia, lower abdominal pain, and dysmenorrhea. Four (9%) women had experienced dyspareunia, and this symptom changed after surgery as follows: 1 resolved, 2 improved, and 1 worsened slightly. Five (11%) women had felt lower abdominal pain pre-operatively; after surgery, 2 resolved, 2 improved, and 1 worsened slightly. Thirteen (30%) women had complained of dysmenorrhea pre-operatively; after surgery, 2 resolved, 7 improved, and 4 experienced no change (Figure 3).

One (2%) patient underwent another gynecological surgery after the vaginal ovarian cystectomy, which was contralateral ovarian cystectomy.

A 5-point scale was used to evaluate the transvaginal ovarian surgery (Figure 4). Two (5%) women answered that it was unsatisfactory: one was the patient who felt temporary dyspareunia, and the other was the patient who underwent another gynecological operation after vaginal ovarian cystectomy. Sixteen (36%) women felt that the operation had been excellent. The average score was 4.12 with an SD of 0.82.

Discussion

In a questionnaire survey, it is important that the respondents represent all patients surveyed. Sixty percent of patients responded to our questionnaire, and their characteristics were very similar to those of the overall patients. The responders seemed to be representative of the patients who underwent the transvaginal surgery.

With regard to fertility, responders under 40 years of age were evaluated. Of the 40 responders under the age of 40 years, 24 reported that they did not use contraception, and their pregnancy rate was 38%. If this group consisted of only women who were actively trying to conceive, this pregnancy rate might be lower than the pregnancy rate of women in this age group. In this group without contraception, there were 4 women who had their first intercourse 5, 5, 6, and 12 months, respectively, after surgery, suggesting that this group consisted both of women who tried to have a baby and those who were unconcerned about coitus or conception. The three women who had their first intercourse 5, 6, and 12 months, respectively, after surgery were all 30 years old or over. The pregnancy rate in women under the age of 30 years was 60%, which is equivalent to the pregnancy rate in women under the age of 30 years who desire to have a child (14). This finding may indicate that transvaginal surgery does not interfere

with conception in women with a desire to have a child. With respect to the relationship between the duration of the postoperative period and the pregnancy rate, although not statistically significant, the pregnancy rate of women 18 months and longer after surgery was higher than that of women under 18 months, suggesting that the cumulative pregnancy rate may increase with the time from surgery.

A total of 12 pregnancies was identified. The rate of spontaneous abortion was 16%, which is equal to the abortion rate of women in this age group (15). Five vaginal deliveries were successfully achieved without complications. In this survey, there was no evidence suggesting that transvaginal surgery caused abortions or abnormal deliveries, including vaginal wall laceration.

Dyspareunia developing after transvaginal surgery is one of the most important issues to be clarified. According to the questionnaire survey of gynecologists, 69% was concerned about dyspareunia as a long-term problem (7). In this survey, 2 (5%) women complained of temporary dyspareunia after surgery. This pain developed 1 month after surgery and disappeared 2 months after surgery. No women complained of lasting dyspareunia. The 2 women with dyspareunia had sexual intercourse 1 month after surgery. Absorbable sutures usually remain on the vaginal wall 1 month

after surgery, and at least 6 weeks are needed for withdrawal of sutures and wound healing. The early sexual intercourse may have resulted in temporary pain from an unhealed wound. Patients may need to be told to avoid sexual intercourse for at least 6 weeks after surgery.

In the current survey, no patients developed permanent dyspareunia due to the operative scar on the vaginal wall. A poorly executed culdotomy may be associated with dyspareunia because it scars the vaginal wall. The deviated wound to the uterine side may also be problematic, because the operation scar near the uterus limits the pitching of the uterus during sexual intercourse, leading to dyspareunia. Inadequate culdotomy may cause permanent dyspareunia. In order to prevent dyspareunia, a reliable technique of culdotomy is needed for transvaginal surgery. Culdotomy 2U or Culdotomy 4S2U is the technique that we recently described for the transvaginal approach in ovarian cystectomy or NOTES, in which transvaginal ultrasound guidance accurately identifies the entry point into the peritoneal cavity (11,12). A vaginal ultrasound probe with a needle guide is inserted into the vagina, and the vaginal wall is punctured with an umbrella Hakko needle via the center of the posterior vaginal fornix. The needle penetrating from the vaginal side toward the cul-de-sac is a useful guide for

accurate incision of the vaginal wall. Visualization by ultrasound and centesis by the needle prevent intestinal and rectal injuries and always lead to successful culdotomy.

This technique was used in 57 (78%) of 73 cases without complications, including rectal injury. This questionnaire survey demonstrated that Culdotomy 2U or 4S2U was useful in preventing postoperative dyspareunia.

Two (5%) women complained of abnormal genital bleeding. In 1 case, the genital bleeding disappeared spontaneously 2 months after surgery; it is thought that early sexual intercourse resulted in bleeding from an unhealed wound. The other bleeding occurred regularly in the middle of the menstrual cycle, likely due to ovulatory bleeding from ovarian dysfunction because of its regular occurrence between menstruations. During the observation period of all patients, small granulations were found in the vaginal wounds of 3 (4%) outpatients. These were removed with liquid nitrogen beforehand, to avoid contact bleeding caused by granulations.

Three (7%) women with endometriomas complained of dysmenorrhea that occurred only after surgery. One possibility is deterioration of endometriosis with time, and the other is implantation of endometrial tissue into the vaginal wall (16). The 3 other women with endometriomas already had dysmenorrhea before surgery; 2 improved, and

1 had no change. Although we cannot judge whether the transvaginal approach for removal of endometriomas aggravates endometriosis, the use of transvaginal surgery in patients with endometriosis should be considered carefully.

With respect to changes in pre-existing discomfort, the decreases in dysmenorrhea and lower abdominal pain are worth mentioning. Of the 13 women who complained of dysmenorrhea, 9 (69%) reported improvement after surgery, and none felt worse. Of the 5 women who complained of lower abdominal pain, 4 (80%) reported improvement. The decrease in dysmenorrhea may be a good side effect of culdotomy. Laparoscopic uterosacral nerve ablation is known to be a therapy for dysmenorrhea; in this procedure, the destruction of the nerves in the uterosacral ligament leads to the decrease in dysmenorrhea (17). In culdotomy, the vaginal wall between bilateral uterosacral ligaments is incised without incising the ligaments themselves. Although the precise reason is not clear, the destruction of nerves between the ligaments by culdotomy may be associated with the mechanism responsible for decreasing dysmenorrhea.

Overall patient satisfaction with surgery was evaluated on a 5-point scale. The majority of patients had a high opinion of their transvaginal surgery. In the “remarks”

column, some patients expressed their gratitude for the lack of pain after surgery, their early recovery, and the absence of abdominal scars. This result shows that transvaginal surgery is quite acceptable for young patients.

The present survey shows that transvaginal surgery, with an adequate culdotomy, causes neither infertility nor dyspareunia and suggests that dysmenorrhea might be reduced, except in cases of endometrioma. Many young patients found transvaginal surgery satisfactory. The transvaginal approach for the removal of intraperitoneal organs in young women appears to be reasonable.

Disclosures

Drs. Masaaki Tanaka, Tetsuya Sagawa, Rena Yamazaki, Subaru Myojo, Satoshi Dohi,
and Prof. Masaki Inoue have no conflicts of interest or financial ties to disclose.

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Figure Legends

Figure 1. Pregnancy by age (a) and pregnancy rate of women under the age of 30 years (b)

Gray boxes indicate pregnant women.

Figure 2. Time to first intercourse after surgery and dyspareunia

Gray boxes indicate women who complained of dyspareunia.

Figure 3. Change in dysmenorrhea

The bar indicates the change in dysmenorrhea that existed before surgery.

Figure 4. Evaluation of surgery by patients on a 5-point scale